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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,145	07/18/2003	George K. Stookey	22076-2	5211

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EXAMINER
SAYALA, CHHAYA D

ART UNIT	PAPER NUMBER
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,145	STOOKEY, GEORGE K.	
	Examiner	Art Unit	
	C. SAYALA	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/29/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/29/2007 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spanier et al. (US Patents 5011679 and 5114704) in view of Witt et al. (U Patent 6350438) and further in view of Perlberg et al. (US Patent 6223643).

Both the Spanier patents teach rawhide being coated with inorganic polyphosphate with the formula $M_{n+2}P_nO_{3n+1}$, n=3, (see col. 12, lines 6-13 in both), wherein the pyrophosphates are known to be anti-tartar, anti-plaque or anti-calculus agents. (Col. 9, lines 55-60, col. 9, lines 58-59, respectively). In Spanier '704 , the

patentees teach that the coated rawhide can be used for both dogs as well as cats (col. 14, lines 25+ in '704). Also, note the amounts of pyrophosphate in Table 1, 0.25-5%. The patentees also teach using such a coating on other dog foods, such as biscuits. The patent teaches packaging such products. It would therefore, have been obvious to package the rawhide coated product too, and packaging such rawhide chews is a commonplace expedient as any store which sells such products will show. The patent does not teach tripolyphosphates ($Na_5P_3O_{10}$) per se or cetyl pyridinium salts.

Witt et al. teach antiplaque antimicrobial agents in an amount of at least .01% by weight . See cetyl pyridinium chloride shown at col. 16, line 43, as such an agent. The patent also discloses tripolyphosphate as an anti-calculus agent in an amount 1.5-15%. See col. 14, line 51, col. 15, lines 17-23, line 40 and specifically line 32. The composition is applied to chews such as rawhide (col. 19, lines 7, 10-11) or even incorporated into the rawhide product (lines 9-11, col. 19). Witt et al. specifically teach that tripolyphosphate may be used in place of pyrophosphates, suggesting therefore, the replacement of pyrophosphate of Spanier et al. with tripolyphosphate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply on or incorporate in rawhide, such as that of Spanier et al. with the polyphosphate of Witt et al. for its benefit as an anti-calculus agent and to combine such a composition with cetyl pyridinium salt, also disclosed by Witt et al., for its established benefit as an antimicrobial agent. To apply the amounts or to optimize the ranges shown by the above references when such a combination is made would have been within the realm of the artisan, bearing in mind the usefulness of the two

ingredients, each for its established utility and benefit for rawhide application. To provide the number of chews to a pet would have been obvious also, depending on the advice of a veterinarian or as desired by the pet owner. With regard to claims 3 and 4 or 22, Perlberg et al. is exemplary in teaching the formation of rawhide chews in which at least one antimicrobial is used for treating the rawhide which is chopped to bits before being mixed with the other ingredients as well as a binder (col. 4, line 51+). Therefore to follow such a patent and then to apply the composition of the combination of an anticalculus agent and an antimicrobial agent both shown as being useful when applied to a rawhide by the Witt et al. reference, would have been obvious.

Response to Arguments

Applicant's arguments filed 11/29/2007 have been fully considered but they are not persuasive.

The declaration and arguments presented have been carefully reviewed. The declaration states, at paragraphs # 6 and #7, pointing to Table 1 of the specification (i.e., example 1) and example 2, Table 2, that by incorporating STP and CPC together in amounts 0.72% and 0.04% respectively, applicant obtained a significant reduction in gingivitis and calculus, dental plaque and mouth odor. While it is agreed that Table 2 does in fact establish a significant reduction in gingivitis for the amounts of STP and CPC as 0.72% and 0.04, the instant claims are not limited to these amounts nor are

they limited to gingivitis. With respect to the instant claims vis-à-vis the results for calculus and plaque as presented in Table 2, applicant is respectfully reminded that it is well established that the advantage relied upon must be a significant advantage. See *In re Nolan*, 193 USPQ 641. Example 1 of the specification, shows a decrease in antimicrobial activity *in vitro* and is of lesser probative value because the product claimed includes a chew substrate and it is not clear that the results can be applied to a chew, since the specification states at page 9, lines 28-31, that the effectiveness may vary with the amount, which in turn varies with the nature of the chew and the animal species.

Further, applicant's declaration points to the submitted Rawlings reference (paragraph 11 of declaration), which shows that when a chew product with or without 0.12% chlorohexidine was administered to the animal, it provided no difference to the degree of gingivitis or the amount calculus.

At paragraph 12, applicant points to the now submitted Brown reference, which is a study that includes a dental chew product alone and a dental chew product with 0.2% of a natural antimicrobial agent, and which did not produce significant reduction in plaque, calculus and gingivitis, and did not improve the efficacy of the product.

In response to these refrence submissions and consideration of the same, Rawlings et al. is of little probative value because Witt et al. and Glandorf et al. teach the claimed composition as an effective anti-plaque and anti-calculus combination, Witt et al. particularly advocating the application of such a composition to rawhide chews.

Furthermore, 0.12% chlorohexidine is the only amount disclosed, whereas the majority of the instant claims are open to *any* amount of STP and CPC.

The Brown reference also does not provide the necessary indicia to establish patentability. The reference is restricted to a combination of a chew product and 0.2% of a natural antimicrobial agent. There is nothing on record to relate the natural antimicrobial agent to either the claimed CPC or STP. Therefore, it is not clear what this reference establishes in terms of the claimed combination of CPC and STP with a chew substrate.

As for applicant's arguments, beginning at page 8 (see *Remarks*) he states:

> As averred by Dr. Stookey, at the filing date of this application, "...it would not have been possible to predict beforehand whether the incorporation of cetyl pyridinium chloride in the combination with STP in an animal chew product would provide a dental health benefit to animals." Dr. Stookey notes that none of the references cited in the current rejection describes any experiment in any animal. Dr. Stookey then goes on to cite examples from literature in which active agents (antimicrobial agents) that were known to be effective in other contexts were tried in animal chew products, but failed to demonstrate efficacy when tested on animals.

In response, whether the references have "experimented" with these compositions in animals or not, Witt et al explicitly teach the same composition to be applied to chews, and the lack of experimental data on animals does not render a valid patent non-enabling since it is well established that a reasonable expectation of success, not absolute predictability is necessary for conclusion of obviousness, *In re Longi*, 225 USPQ 545, *In re Morston*, 1961 C.D. 330, *In re Clinton*, 188 USPQ 365, *In re O'Farrell*, 7 USPQ2d 1673, 1681 (Fed Cir 1988). By showing both compounds for oral

care to be applied to rawhide chews the reference has more than suggested the claimed invention.

The remaining remarks at pages 9 onwards pertain to the declaration, which have already been addressed above.

Applicant's amended claims now recite a chew product that comprises CPC and STP (see for example, claim 1):

"wherein the animal chew product is effective to reduce the incidence of both gingivitis and dental calculus in an animal that chews the animal chew product."

Such a limitation constitutes use terminology and does not serve to distinguish the product shown by the combination of reference applied, such a combination that includes Witt et al. For composition claims, intended use of an otherwise old or obvious composition cannot render a claim patentable. *In re Zierden*, 162 USPQ 102, *In re Jone*s, 50 USPQ 48, *In re Spada*, 15 USPQ 2d, 1655, *In re Thuau* 57 USPQ 324.

Claim 12 recites a method for "oral care" and depends from claim 1, the product claim.

Claim 16 recites a method of manufacturing an animal chew product. Again the limitation, "wherein the animal chew product is effective to reduce the incidence of both gingivitis and dental calculus in an animal that chews the animal chew product", does not establish patentability in a method of manufacture claim since only the recited steps of making the product are relied on to establish patentability of such a process of making and not the use of the product being made.

Conclusion

This is a continuation of applicant's earlier Application of the same No. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Sayala whose telephone number is (571) 272-1405. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

C. SAYALA
Primary Examiner
Group 1700.